

Attorney Docket No. P70555US0  
Application No. 10/532,348

**Remarks/Arguments:**

Claims 3-5 are pending.

Claims 1 and 2 are cancelled, without prejudice or disclaimer.

New claims 3 and 4 correspond to previously presented claims 1 and 2, respectively, rewritten to more clearly define the instant invention. New claim 5—dependent on present claim 3—contains subject matter found in the present specification (page 2, last, incomplete ¶).

Claims 1 and 2 were rejected under 35 USC 112, ¶1, for allegedly lacking enablement. Reconsideration is requested.

The PTO argues that enablement is lacking because the specification allegedly fails to describe "how" the presently claimed method "dispenses with body related conversion factors" (Office Action, page 2). With all due respect, the allegation is incorrect.

First of all, "how" the presently claimed method "dispenses with body related conversion factors" is simply by not using them.

Secondly, as taught in subject application (page 1, first 2 paragraphs), the prior art "gold standard" for determining "gastric emptying"—by measuring dwelling time of a test substance in the stomach—involved orally administering radioactive isotope <sup>99m</sup>Tc-protein colloid—as the test substance—and using scintigraphy to measure the dwelling time of this radioactive isotope in the stomach. As also taught in subject application (paragraph bridging pages 2 and 3), in order to get results close to those obtained using the scintigraphy "gold standard," prior art breath-test methods to determine "gastric emptying" used calculations of "tedious body-related conversion factors."

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In accordance with the presently claimed invention, and contrary to the accepted wisdom in the art, applicant found the presently claimed method—by which the tedious "body-related conversion factors are dispensed with"—to be superior to scintigraphy, which can even be, and often is, incorrect. Moreover, since scintigraphy requires ingestion of radioactive material, it could not be repeated several times on the same patient.

Accordingly, the skilled artisan being well aware of body-related conversion factors, since they are already known in the art, providing the same information in a patent specification would be redundant. *Staehelin v. Secher*, 24 USPQ2d 1513, 1516 (BPA&I 1992) ("in satisfying the enablement requirement, an application need not teach, and preferably omits, that which is well known in the art"). A "patent need not disclose, and preferably omits, that which is well known in the art." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 94 Enablement under §112, ¶1, is determined from the viewpoint of one of ordinary skill in the art. *In re Smythe*, 178 USPQ 279 (CCPA 1973). The person of ordinary skill in the art brings with him a knowledge and understanding of the entirety of the prior art—including body-related conversion factors—up until the date of application. See *In re Stephens*, 188 USPQ 659, 661 (CCPA 1976).

In view of the foregoing remarks, the rejection of claims under §112, ¶1, for allegedly lacking enablement, is overcome. Withdrawal of the rejection appears to be in order.

The objection to claims 1 and 2 is overcome by rewriting the claims—as present claims 3 and 4, respectively—as set forth above. Applicant wishes to thank the examiner for kindly suggesting claim language to overcome the objection.

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Claims 1 and 2 were rejected under 35 USC 101 for allegedly constituting non-statutory subject matter. Reconsideration is requested.

The rejection cannot be maintained because it is legally erroneous. That is, the rejection relies on legal standards—and cited case law applying the stated legal standards—applied only to claims involving computer-related subject matter. See MPEP 2106.01 ("Computer-Related Nonstatutory Subject Matter").

Since the present claims do not involve computer-related—non-statutory or otherwise—subject matter, the rejection is overcome. Withdrawal of the rejection appears to be in order.

Claim 1 was rejected under 35 USC 102(e) as being allegedly anticipated by US 7,338,444 (Ben-Oren). Reconsideration is requested.

For anticipation under § 102 to exist, each and every claim limitation, as arranged in the claim, must be found in a single prior art reference. *Jamesbury Corp. v. Litton Industrial Products, Inc.*, 225 USPQ 253 (Fed. Cir. 1985). The "absence" from a prior art reference of a single claim limitation "negates anticipation." *Kolster Speedsteel A B v. Crucible Inc.*, 230 USPQ 81, 84 (Fed. Cir. 1986). To anticipate the claim, each claim limitation must "identically appear" in the reference disclosure. *Gechter v. Davidson*, 43 USPQ2d 1030, 1032 (Fed. Cir. 1997). To be novelty defeating, a reference must put the public in possession of the identical invention claimed. *In re Donahue*, 226 USPQ 619 (Fed. Cir. 1985).

Ben-Oren discloses a test method for gastric emptying breath tests (GEBT). Looking at the description on column 16, line 21, the breath samples are analyzed and—as can be derived from lines

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31 and 39—complicated calculations are used involving factors based on "the height and weight of the subject being tested" (line 43). Thus, in contrast to the presently claimed invention—which excludes use of body-related conversion factors (i.e., "body-related conversion factors are dispensed with")—Ben-Oren teaches a method requiring use of body related conversion factors.

Accordingly, the "absence" from Ben-Oren of the limitation—on the rejected (and present) claims—that excludes body-related conversion factors "negates anticipation" by Ben-Oren. *Kolster Speedsteel A B*, 230 USPQ at 84. Ben-Oren fails to anticipate the rejected (and present) claims because the "claim limitation" excluding body-related conversion factors does not "identically appear" in the reference disclosure. *Gechter*, 43 USPQ2d at 1032. Ben-Oren is not novelty defeating because the reference put the public in possession of the identical invention claimed. *Donahue, supra*.

In view of the foregoing remarks, the rejection of claims under §102(e), as allegedly anticipated by Ben-Oren, is overcome. Withdrawal of the rejection appears to be in order.

Claim 2 was rejected under 35 USC 103(a) as being allegedly unpatentable over Ben-Oren in view of GB2360845 (Ghoos). Reconsideration is requested.

To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art," *In re Wilson*, 165 USPQ 494, 496 (CCPA 1970), "and it is error to ignore specific limitations distinguishing over the [prior art] reference." *Ex parte Murphy*, 217 USPQ 479, 481 (PO Bd. App.

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1982). A "ground of rejection is simply inadequate on its face . . . [when] the cited references do not support each limitation of [the] claim." *In re Thrift*, 63 USPQ2d 2002, 2008 (Fed. Cir. 2002).

The rejection under § 103(a) cannot be maintained for the same reasons (set forth above) that the rejection under § 102(e) cannot be maintained. As explained above, Ben-Oren does not support the limitation—on the rejected (and present) claims—excluding use of "body-related conversion factors," and Ghoos provides nothing to cure the fatal deficiency in Ben-Oren; i.e., Ghoos in combination with Ben-Oren does not support excluding the body-related conversion factors required for use in the Ben-Oren method.

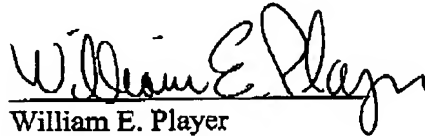
Accordingly, since "the cited references do not support each limitation of [the] claim[s]"—both rejected and present—the rejection citing Ben-Oren and Ghoos, under § 103(a), is "inadequate on its face." *Thrift*, 63 USPQ2d at 2008. A case of *prima facie* obviousness is not established because all limitations on the rejected (and present) claims are neither taught nor suggested by the prior art relied on to reject the claims. *Royka, supra*.

In view of the foregoing remarks, the rejection of claims under § 103(a), based on the combined teachings of Ben-Oren and Ghoos, is overcome. Withdrawal of the rejection appears to be in order.

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Favorable action is requested.

Respectfully submitted,



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